5. 510(K) SUMMARY

Submitter's Name:	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Submitter's Telephone:	512-381-7080
Submitter's Fax:	800-817-4938
Contact Name:	William W. Sowers
Date Summary was Prepared:	4-Feb-13
Trade or Proprietary Name:	Genesys Spine Apache™ IBFD Star Cervical System
Common or Usual Name:	Intervertebral Body Fusion Device, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Codes:	ODP
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Legally Marketed (unmodified) device:	Genesys Spine Apache™ Cervical Interbody System (K103034) BAK/Cervical Interbody Fusion System (P980048) Eminent Spine Copperhead IBFD (K090064)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine Apache™ IBFD Star Cervical System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of a Genesys Spine cervical interbody fusion device, which may be implanted as a single device via an anterior approach.

INDICATIONS FOR USE

The Genesys Spine Apache™ IBFD Star Cervical System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

TECHNICAL CHARACTERISTICS

The Genesys Spine Apache™ IBFD Star Cervical System is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The Genesys Spine Interbody Fusion System implant components are made of polyether ether ketone (Invibio PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device. The additional implant offering being proposed has similar technological characteristics and identical indications as the currently cleared product line.

Results of non-clinical testing relative to static and dynamic testing per ASTM F2077-03, subsidence testing per ASTM F2267-04, and expulsion testing per ASTM draft standard F-04.25.02.02 were used to determine substantial equivilence.

PERFORMANCE DATA

The Genesys Spine Apache™ IBFD Star Cervical System was tested in static and dynamic axial compression and torsion per ASTM F2077-11, static subsidence per ASTM F2267-04, and expulsion testing per ASTM draft standard F-04.25.02.02.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Genesys Spine Apache™ IBFD Star Cervical System is substantially equivalent to the Genesys Spine Apache™ Cervical Interbody System, the Centerpulse BAK/Cervical Interbody Fusion System, and the Eminent Spine Copperhead IBFD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2013

Genesys Spine
Mr. William W. Sowers
Vice President of Quality and Regulatory
1250 Capital of Texas Highway South, Building Three, Suite 600
Austin, Texas 78746

Re: K130317
Trade/Device Name: Genesys Spine Apache™ IBFD Star Cervical System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 25, 2013
Received: November 1, 2013

Dear Mr. Sowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Device Name: Genesys Spine Apache™ IBFD Star Cervical System

The Genesys Spine Apache™ Interbody Fusion Device Star Cervical System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices